



General

Guideline Title

Evidence-based care guideline for prevention and management of acute gastroenteritis (AGE) in children aged 2 months to 18 years.

Bibliographic Source(s)

Cincinnati Children's Hospital Medical Center. Evidence-based care guideline for prevention and management of acute gastroenteritis (AGE) in children aged 2 months to 18 years. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Dec 21. 21 p. [116 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Cincinnati Children's Hospital Medical Center. Evidence-based clinical care guideline for acute gastroenteritis (AGE) in children aged 2 months through 5 years. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2006 May. 15 p. [50 references]

Recommendations

Major Recommendations

The strength of the recommendation (strongly recommended, recommended, or no recommendation) and the quality of the evidence $(1a\hat{a} \in `5)$ are defined at the end of the "Major Recommendations" field.

Prevention

- 1. It is recommended that infants be immunized against rotavirus according to the Advisory Committee on Immunization Practices (ACIP) recommendations, including during mild acute gastroenteritis (AGE) (Soares-Weiser et al., 2010 [1a]; Staat et al., 2011 [3a]; Committee on Infectious Diseases & American Academy of Pediatrics [AAP], 2009 [5]; Cortese & Parashar, 2009 [5]). See Appendix 1 in the original guideline document.
- 2. It is recommended that families be instructed on the benefit of:
 - Hand hygiene in the prevention of transmission of AGE in the home and at day care (Ejemot et al., 2008 [1a]), and
 - Breastfeeding as a protective practice against severe AGE in infants (Lamberti et al., 2011 [1a]; Dennehy et al., 2006 [4a]; Van der Wielen & Van Damme, 2008 [5]).

Note: Overall evidence demonstrates a protective effect of probiotics against AGE in children. Due to lack of specific evidence of cause of diarrhea, organism(s), dosage, and product availability, a specific recommendation for the use of probiotics in prevention of AGE is unable to be made (Sazawal et al., 2006 [1a]; Hojsak et al., "Lactobacillus GG in the prevention of nosocomial," 2010 [2a]; Hojsak et al., "Lactobacillus GG in the prevention of gastrointestinal," 2010 [2a]; Lin et al., 2009 [2b]).

Assessment

Clinical Assessment

- 3. It is recommended that the history and physical examination be the primary basis for the diagnosis of AGE (Porter et al., 2003 [3a]; Local Consensus, 2011 [5]; King et al., 2003 [5b]).
- 4. It is recommended that weight on presentation be documented as a baseline to guide rehydration therapy if needed (Steiner, DeWalt, & Byerley, 2004 [1b]; Snaith, Peutrell, & Ellis, 2008 [4b]).
 - Note: Acute weight loss based on a recent, documented pre-illness weight, as might be available in the office setting, is the most reliable measure of dehydration status on presentation (Steiner, DeWalt, & Byerley, 2004 [1b]).
- 5. It is recommended that clinical assessment be initially performed for the presence and degree of dehydration (none, some or severe) (Steiner, DeWalt, & Byerley, 2004 [1b]; Duggan et al., 1996 [2a]; King et al., 2003 [5b]). See Table 2 in the original guideline document for a Clinical Dehydration Scale (CDS), valid for children under age 5 years (Friedman et al., 2004 [2a]).
 - Note 1: Although the CDS is the tool with the most published evidence of validity, other clinical signs and symptoms have been shown to be helpful in diagnosing degree of dehydration, and severe dehydration can exist even in the absence of a toxic appearance (Gorelick, Shaw, & Murphy, 1997 [3a]). See Appendix 2 and Appendix 3 in the original guideline document for additional tools and information regarding clinical assessment for dehydration.
 - Note 2: A meta-analysis of clinical signs and symptoms of dehydration in children identified abnormal capillary refill time as the most useful individual sign for predicting some dehydration (likelihood ratio [LR], 4.1; 95% confidence interval: 1.7, 9.8) against a gold standard of rehydration weight. As capillary refill time is not included in the CDS, it is prudent to include it in the routine assessment for dehydration (Steiner, DeWalt, & Byerley, 2004 [1b]).

Laboratory Studies

- It is recommended that laboratory tests not be routinely performed in children with signs and symptoms of AGE; e.g., serum electrolytes, tests for specific pathogens, and urinary indices (Steiner, DeWalt, & Byerley, 2004 [1b]; Steiner, Nager, & Wang, 2007 [3b]; Local Consensus, 2011 [5]).
 - Note 1: Serum electrolytes are sometimes useful in assessing children with dehydration and who require intravenous (IV) fluids. In the absence of evidence-based criteria to direct selective electrolyte screening, clinical judgment regarding when to obtain electrolyte studies is superior to routine screening in protecting children from unnecessary testing (Steiner, DeWalt, & Byerley, 2004 [1b]; Wathen, MacKenzie, & Bothner, 2004 [3b]; Parkin et al., 2010 [4b]; Local Consensus, 2011 [5]; Rhee & Silverstein, 2005 [5]; Steiner, DeWalt, & Byerley, 2005 [5]; Tarini & Mendoza, 2005 [5]).
 - Note 2: Consider obtaining stool testing if there is a specific pathogen community outbreak; or for children who are less than 3 months of age, have grossly bloody stools, are immunocompromised, septic, toxic, or who have a history of foreign travel (Guarino et al., 2008 [5a]). A specific pathogen community outbreak may trigger health department testing requirements prior to return to day care (Ohio Administrative Code, 2009 [5]).

Management

Rehydration: Some or No Dehydration

- 7. It is recommended that children with some or no dehydration, including those with recurrent vomiting, be managed by frequent phone or office/urgent care follow up and, on occasion, emergency department encounters (Local Consensus, 2011 [5]; Guarino et al., 2008 [5a]).
- 8. It is recommended, for the child with some or no dehydration:
 - Use of the child's preferred, usual, and age appropriate diet and fluids (Brown, Peerson, & Fontaine, 1994 [1b]; Fayad et al., 1993 [2a]; Alarcon et al., 1992 [2b]; Margolis et al., 1990 [2b]), and
 - Offer commercial oral rehydration solution (ORS), if tolerated and if losses exceed intake, until an adequate degree of rehydration is achieved (Hartling et al., 2006 [1a]; Fonseca, Holdgate, & Craig, 2004 [1a]). See Table 3 in the original guideline document for suggested directions for use. See Appendix 4 in the original guideline document for information on specific ORS options.
 - Offer about 10 mL/kg of ORS for each loose stool or vomiting episode (Armon et al., 2001 [5a]).
- 9. It is recommended that the following not be used:
 - Restrictive or progressive diets (Alarcon et al., 1991 [2b]; Margolis et al., 1990 [2b]; Khin et al., 1985 [2b]; Placzek & Walker-Smith, 1984 [2b])
 - A clear liquid diet (King et al., 2003 [5b]) (see Appendix 4 in the original guideline document)
 - Diluted milk or formula (Brown, Peerson, & Fontaine, 1994 [1b])

• Lactose-free formula, unless previously-known lactose intolerance is present (Brown, Peerson, & Fontaine, 1994 [1b])

Rehydration When Intravenous (IV) Therapy Is Chosen

- 10. It is recommended,
 - When unable to replace the estimated fluid deficit and keep up with the on-going losses using oral feedings alone, and/or
 - For severely dehydrated children,

That a bolus of IV isotonic solution (i.e. lactated Ringer's solution or normal saline) be administered until signs of dehydration have been reversed.

Suggested initial therapy:

• 20mL/kg body weight bolus over 30 to 60 minutes with reassessment and repeat if necessary (Hartling et al., 2006 [1a]; Fonseca, Holdgate, & Craig, 2004 [1a]; Nager & Wang, 2010 [2b]; Neville et al., 2006 [2b]; Spandorfer et al., 2005 [2b]; King et al., 2003 [5b]; Khanna et al., 2009 [5]).

Note 1: Two small studies by a single author demonstrated that initial bolus therapy at a rate of 50 mL/kg body weight is a viable alternative (Nager & Wang, 2010 [2b]; Nager & Wang, 2002 [2b]).

Note 2: Nasogastric (NG) as compared to IV rehydration is as efficacious, is no more labor intensive, and is associated with fewer complications (Rouhani et al., 2011 [1b]). For the purposes of this guideline NG may be substituted for IV rehydration, but due to its infrequent use at Cincinnati Children's Hospital Medical Center (CCHMC), it is not otherwise mentioned in this document. It is appropriate to involve the family in the decision regarding the selection of IV versus NG for fluid replacement.

Oral and IV Fluids After Initial Rehydration Bolus

- 11. It is recommended that the child treated with IV fluids continue, as soon as tolerated, with:
 - A preferred, usual, and age appropriate diet and fluids, which may include commercial ORS (Fayad et al., 1993 [2a]; Cohen et al., 1995 [2b]; Fox et al., 1990 [2b]; Hjelt et al., 1989 [2b]; Khin et al., 1985 [2b]), and
 - About 10 mL/kg of ORS for each loose stool or vomiting episode (Armon et al., 2001 [5a]).
- 12. It is recommended that ongoing reassessment of hydration status and tolerance of oral rehydration therapy (ORT) be used to guide the need for and choice of IV fluids after initial isotonic bolus:
 - For the hydrated child able to tolerate oral rehydration therapy, discontinue IV therapy
 - For the child not fully hydrated upon reassessment, give additional isotonic fluids as a bolus
 - For the hydrated child unable to tolerate sufficient oral rehydration therapy to replace losses
 - Give half-normal saline with 5% dextrose at a maintenance volume plus calculated replacement for losses
 - After child begins to urinate (or if serum electrolytes are known to be normal) add 20 mEq/L potassium chloride (Kannan et al., 2010 [2a]; Neville et al., 2010 [2a]; Montanana et al., 2008 [2a]; Yung & Keeley, 2009 [2b]; Drysdale et al., 2010 [4a]; Hanna & Saberi, 2010 [4a]; Snaith, Peutrell, & Ellis, 2008 [4b]; Holliday & Segar, 1957 [5])

Note 1: Patients with abnormal plasma sodium levels or abnormal kidney function are excluded from the target population for this guideline and from all of the cited studies for this recommendation. Individual consideration for these patients is particularly important regarding maintenance fluids.

Note 2: The grade of the body of evidence is high for not using less than 0.45% saline during the first 24 hours of IV fluid therapy for children with normal kidney function (Kannan et al., 2010 [2a]; Yung & Keeley, 2009 [2b]; Hanna & Saberi, 2010 [4a]).

Inpatient Management

- 13. It is recommended that a child be admitted for inpatient care when:
 - The child is severely dehydrated
 - The child has intractable vomiting
 - The child is unable to maintain hydration orally due to vomiting or diarrhea losses
 - Caregivers cannot provide adequate care at home and/or there are social or logistical concerns

(Local Consensus, 2011 [5]; Guarino et al., 2008 [5a]).

14. It is recommended, if the child requires IV fluids for more than 24 hours, or if reassessment reveals evidence of fluid or electrolyte

imbalance, that selection and adjustment of IV fluid and rate of administration be based on sound principles and ongoing reassessment including:

- Frequent clinical assessment
- Daily weights, and
- Regular electrolyte monitoring as clinically indicated, at minimum every 2 to 3 days

(Neville et al., 2005 [3b]; Drysdale et al., 2010 [4a]; Moritz & Ayus, 2010 [5]; Holliday, Ray, & Freidman, 2007 [5]; Guarino et al., 2008 [5a]).

Note: Strict intake and output measurements (I/O) are ideal to guide therapy. However, standardized measured daily weights are less burdensome to obtain and are sufficient to guide therapy, while inaccurate I/O measurements are inadequate (Drysdale et al., 2010 [4a]; Snaith, Peutrell, & Ellis, 2008 [4b]).

Adjunct Therapy

There is a growing body of literature establishing the effectiveness of selected probiotics as an adjunct to rehydration therapy in simple AGE. Proven efficacy is organism- and dose-dependent and there is no evidence of efficacy for most probiotic products (see Appendix 5 in the original guideline document for product information). In developed countries, *Lactobacillus rhamnosus* GG (LGG) given in a daily dose of 10 billion colony forming units per day (CFU/day) has proven efficacy, particularly in rotavirus, to reduce the duration of diarrhea, the risk of protracted diarrhea and the duration of hospitalization (Szajewska et al., 2007 [1a]; Guarino et al., 2008 [5a]).

- 15. It is recommended to talk to parents before making a decision about probiotic use. If a family chooses to use a probiotic, it is important to assure selection of an effective product (see Appendix 5 in the original guideline document).

 To obtain best efficacy:
 - Use a dose of at least 10 billion CFU/day of LGG (see Appendix 5 in the original guideline document regarding product availability)
 - Start treatment as soon as possible
 - Treat for a total of 5 to 7 days

(Szajewska, Skorka, & Dylag, 2007 [1a]; Szajewska et al., 2007 [1a]; Guandalini et al., 2000 [2a]; Local Consensus, 2011 [5]; Guarino et al., 2008 [5a]; Harris et al., 2008 [5a]).

Note: Parameters influencing the family's decision to use probiotics may include:

- Cost
- Evidence of benefit
- Likelihood of rotavirus origin
- Transmission concerns
- Safety

(Allen et al., 2010 [1a]; Szajewska et al., 2007 [1a]; Guandalini et al., 2000 [2a]). See Appendix 5 in the original guideline document for elaboration of these parameters.

Other Therapy

16. It is recommended that antiemetics not be routinely used in the management of children with AGE (Fedorowicz, Jagannath, & Carter, 2011 [1a]; Szajewska, Gieruszczak-Bialek, & Dylag, 2007 [1a]).

Note 1: On 9/15/2011, the U.S. Food and Drug Administration (FDA) notified the healthcare community that ondansetron may increase the risk of developing prolongation of the QT interval of the electrocardiogram. Patients at risk for adverse outcomes include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that lead to QT prolongation (Mehta, Sanatani, & Whyte, 2010 [2b]; FDA, 2011 [5]; McKechnie & Froese, 2010 [5]).

Note 2: Shared decision making may be employed in the consideration of ondansetron use in children with vomiting. Discussion points may include:

- Its use may decrease vomiting during the first hours after presentation
- Its use may decrease the need for IV fluids in the emergency department
- Its use may reduce hospitalization rates in those patients who require IV fluids
- Its use may increase diarrheal episodes

- It has a relatively high cost
- Most studies of ondansetron use in children with AGE have
 - Been performed only on mildly dehydrated children
 - Received funding from the manufacturer of ondansetron
- Its use may increase risk for long QT interval

(Fedorowicz, Jagannath, & Carter, 2011 [1a]; DeCamp et al., 2008 [1a]; Szajewska, Gieruszczak-Bialek, & Dylag, 2007 [1a]; Yilmaz, Yildizdas, & Sertdemir, 2010 [2a]; FDA, 2011 [5]).

- 17. It is recommended that antimicrobial therapies not be used except for cases of culture-proven pathology (Barbara et al., 2000 [3a]; Szajewska & Dziechciarz, 2010 [5]). See AAP Red Book for specifics (AAP, 2009 [5]).
- 18. It is recommended that antidiarrheal agents not be routinely used in the management of children with AGE (King et al., 2003 [5b]; Khanna et al., 2009 [5]).

Discharge Criteria

- 19. It is recommended that for children receiving care in a hospital setting, prompt discharge be considered when the following levels of recovery are reached:
 - Sufficient rehydration achieved as indicated by weight gain and/or clinical status
 - IV fluids not required
 - Oral intake equals or exceeds losses
 - Medical follow up is available via telephone or office visit
 - Adequate family teaching has occurred, including:
 - Hand hygiene at home, day care and elsewhere (see Recommendation #2 above) for prevention of AGE transmission
 - Expected course of illness
 - Prevention of dehydration
 - · Signs of dehydration

(Local Consensus, 2011 [5])

Return to Social Life

- 20. It is recommended that a child with diarrhea of infectious or unknown cause return to day care only when transmission can be reliably prevented, preferably after the diarrhea has ceased (Local Consensus, 2011 [5]; Ohio Administrative Code, 2009 [5]). At minimum:
 - Stools are more formed
 - Stools are not leaking out of the diaper
 - Frequency of diaper changes are able to be handled by day care staff
 - For the toilet trained child, the child can make it to the bathroom without soiling
 - Good hand hygiene is practiced by day care staff
 Note: Negative testing for certain pathogens may be required by law or by the day care facility (Local Consensus, 2011 [5]; Ohio Administrative Code, 2009 [5]).

Definitions:

Table of Evidence Levels

Quality Level	Definition			
1a [†] or 1b [†]	Systematic review, meta-analysis, or meta-synthesis of multiple studies			
2a or 2b	Best study design for domain			
3a or 3b	Fair study design for domain			
4a or 4b	Weak study design for domain			
5	Other: general review, expert opinion, case report, consensus report, or guideline			

 $[\]dagger a = good quality study; b = lesser quality study$

Strength	Definition
"Strongly recommended"	There is consensus that benefits clearly outweigh risks and burdens (or vice versa for negative recommendations).
"Recommended"	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is a lack of consensus to direct development of a recommendation.

Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.

- 1. Grade of the body of evidence
- 2. Safety/harm
- 3. Health benefit to the patients (direct benefit)
- 4. Burden to patient of adherence to recommendation (cost, hassle, discomfort, pain, motivation, ability to adhere, time)
- 5. Cost-effectiveness to healthcare system (balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis)
- 6. Directness (the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome])
- 7. Impact on morbidity/mortality or quality of life

Clinical Algorithm(s)

A clinical algorithm for the evaluation and management for acute gastroenteritis in children aged 2 months to 18 years is provided in the original guideline document.

Scope

Disease/Condition(s)

Acute gastroenteritis

Guideline Category

Diagnosis

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Emergency Medicine

Family Practice

Nutrition			
Pediatrics			
Intended Users			
Advanced Practice Nurses			
Allied Health Personnel			
Dietitians			
Hospitals			
Nurses			
Other			
Patients			
Physician Assistants			
Physicians			
Public Health Departments			

Gastroenterology

Nursing

Guideline Objective(s)

In the target population, the objectives of this guideline are to:

- Decrease use of emergency department (ED) services for management of mild cases
- Improve the likelihood that information provided by triage and school personnel is adherent to guideline recommendations
- Reduce the length of stay in the emergency department and inpatient setting
- Reduce the rate of hospitalizations

Target Population

Inclusions: This guideline is intended primarily for use:

- In children aged 2 months to 18 years of age
- With signs and symptoms of acute gastroenteritis
- With or without accompanying nausea, vomiting, fever, or abdominal pain

Exclusions: This guideline does NOT address all considerations needed to manage those with the following:

- Toxic appearance, shock, or requiring intensive care
- Episodes of diarrhea lasting longer than 7 days
- Previously diagnosed disorders including immunodeficiency or those affecting major organ systems
- Vomiting with no accompanying diarrhea for more than 24 hours
- Acute gastroenteritis (AGE) accompanying failure to thrive
- Diarrhea and/or vomiting accompanied by chronic metabolic disorders (e.g., diabetes, phenylketonuria [PKU])
- Diagnosis of hyponatremic or hypernatremic dehydration
- Diarrhea caused by chronic disease

Diarrhea is defined as three or more loose, watery stools a day.

Interventions and Practices Considered

Prevention

- 1. Immunization against rotavirus per Advisory Committee on Immunization Practices recommendations
- 2. Family instruction in hand hygiene
- 3. Breastfeeding infants

Assessment/Evaluation

- 1. History and physical examination, including weight on presentation
- 2. Assessment of degree of dehydration with use of the Clinical Dehydration Scale (CDS)
- 3. Laboratory studies (not routinely recommended)
 - Serum electrolytes for children who require intravenous (IV) fluids
 - Stool testing in cases of specific pathogen community outbreak
 - Pathogen testing if negative result required for return to daycare

Management

No or Some Dehydration

- 1. Frequent telephone or office/urgent care follow up and, on occasion, emergency department visit
- 2. Usual, age appropriate diet
- 3. Small frequent feedings

Some or Severe Dehydration

- 1. Bolus IV isotonic solution
- 2. Nasogastric rehydration
- 3. Prompt refeeding of usual and age appropriate diet after initial rehydration
- 4. Ongoing reassessment of hydration status and oral rehydration therapy (ORT) tolerance
- 5. Hospitalization
- 6. Reassessment of hydration status as indicated, including clinical assessment, daily weight, and electrolyte monitoring
- 7. Probiotics as adjunctive therapy (Lactobacillus rhamnosus GG)

Other Therapy and Considerations

- 1. Antiemetics and antidiarrheals (not recommended routinely)
- 2. Antimicrobial therapy only in cases of culture-proven pathology
- 3. Patient/parent education
- 4. Discharge criteria
- 5. Patient return to social life

Note: Probiotics as a preventative were considered but not recommended because of lack of specific evidence. The following were considered and not recommended for children with some or no dehydration: restrictive or progressive diets, clear liquid diet, diluted milk or formula, lactose-free formula except in cases of known lactose intolerance.

Major Outcomes Considered

- Length of inpatient stay
- Gastroenteritis admission rate
- Duration of rehydration therapy
- Duration of symptoms
- Cost of treatment

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

To select evidence for critical appraisal by the group for the update of this guideline, the Medline, EMBASE and the Cochrane databases were searched for dates of April 2003 to September 2011 to generate an unrefined, "combined evidence" database using a search strategy focused on answering clinical questions (see Appendix 6 in the original guideline document) relevant to acute gastroenteritis (AGE) for the target population and employing a combination of Boolean searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. The citations were reduced by eliminating duplicates, review articles, non-English articles, and adult articles. The resulting abstracts were reviewed by a methodologist to eliminate low quality and irrelevant references. During the course of guideline development, additional clinical questions were generated and subjected to the search process, and some relevant review articles were identified.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Table of Evidence Levels

Quality Level	Definition
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5	Other: general review, expert opinion, case report, consensus report, or guideline

 $[\]dagger a = good quality study; b = lesser quality study$

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The process by which this guideline was developed is documented in the Guideline Development and Update Process Manual; relevant development materials are kept electronically. The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic search and critical appraisal of the literature, using the Table of Evidence Levels described in the "Rating Scheme for the Strength of the Evidence" field, and examined current local clinical practices.

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference and clinical expertise. During formulation of these recommendations, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

Rating Scheme for the Strength of the Recommendations

Table of Recommendation Strength

Strength	Definition
"Strongly recommended"	There is consensus that benefits clearly outweigh risks and burdens (or vice versa for negative recommendations).
"Recommended"	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is a lack of consensus to direct development of a recommendation.

Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.

- 1. Grade of the body of evidence
- 2. Safety/harm
- 3. Health benefit to the patients (direct benefit)
- 4. Burden to patient of adherence to recommendation (cost, hassle, discomfort, pain, motivation, ability to adhere, time)
- 5. Cost-effectiveness to healthcare system (balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis)
- 6. Directness (the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome])
- 7. Impact on morbidity/mortality or quality of life

Cost Analysis

Prior to the release of rotavirus vaccines in 2006 and 2008 (see Appendix 1 in the original guideline document) significant illness burden in the United States (U.S.) was attributable to AGE, including:

- 12% of hospitalizations of children less than 5 years of age and about 10% of all visits to pediatric emergency departments (ED)
- Approximately 1.5 million outpatient visits, 200,000 hospitalizations and 300 deaths annually
- An annual associated direct cost of \$250 million, with indirect costs of lost work and day care/school of 1 and 2 days, respectively, and

 Approximately one-third of this burden was attributed to rotavirus, which is more likely to cause severe clinical illness and dehydration than non-rotavirus acute gastroenteritis (AGE).

Since the introduction of rotavirus vaccine, disease burden due to AGE, as measured by healthcare utilization and costs, has decreased substantially. See Appendix 1 in the original guideline document for information on the recent and increasing impact of rotavirus vaccine.

Cost-Effectiveness

Post-licensure studies after the first two seasons of rotavirus vaccine use show decreases in costs of 55% to 75%, including medical costs (e.g., ED and hospitalization) and non-medical costs (e.g., lost earnings and family expenses to care for a child with AGE). However, these reductions are not predicted to offset the cost of the vaccine at its current price.

Method of Guideline Validation

Clinical Validation-Pilot Testing

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Upon piloting of the Lactobacillus rhamnosus GG (LGG) recommendation, organizational barriers were addressed as follows:

- Education of clinical staff on the evidence base for the recommendation
- · On-going dissemination of information about the recommendation to incoming teams of rotating clinicians
- LGG as a default order on the electronic medical record order set
- · Availability of product in the organization's inpatient and outpatient pharmacies
- Availability of product to discharged patients in small number of doses from the organization's outpatient pharmacy
- Development of draft patient decision aid for starting or continuing Lactobacillus rhamnosus GG doses (has not been implemented at time of this publication)

The guideline has been reviewed and approved by clinical experts not involved in the development process, distributed to senior management, and other parties as appropriate to their intended purposes. The 2006 version of this guideline was included in a study of guideline quality and judged to be strongly recommended.

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Prevention of transmission and reduction in severity of acute gastroenteritis
- Decreased use of emergency department (ED) services for management of mild cases
- Improvement in the likelihood that information provided by triage and school personnel is adherent to guideline recommendations
- Reduction in the length of stay in the ED and inpatient setting
- Reduction in the rate of hospitalization

Potential Harms

Ondansetron may increase the risk of developing prolongation of the QT interval of the electrocardiogram. Patients at risk for adverse outcomes include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that lead to QT prolongation.

Qualifying Statements

Qualifying Statements

These recommendations result from review of literature and practices current at the time of their formulations. This guideline does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this guideline is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Patient Resources

Quick Reference Guides/Physician Guides

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Cincinnati Children's Hospital Medical Center. Evidence-based care guideline for prevention and management of acute gastroenteritis (AGE) in children aged 2 months to 18 years. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Dec 21. 21 p. [116 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

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Cincinnati Children's Hospital Medical Center

The guideline was developed without external funding.

Guideline Committee

Acute Gastroenteritis Team

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Financial Disclosures/Conflicts of Interest

All Team Members and Anderson Center support staff listed above have signed a conflict of interest declaration and none were found.

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This is the current release of the guideline.

This guideline updates a previous version: Cincinnati Children's Hospital Medical Center. Evidence-based clinical care guideline for acute gastroenteritis (AGE) in children aged 2 months through 5 years. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2006 May. 15 p. [50 references]

[50 references]
Guideline Availability
Electronic copies: Available from the Cincinnati Children's Hospital Medical Center Web site
Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.
Availability of Companion Documents
The following are available:
 Acute gastroenteritis (AGE). Guideline highlights. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2012. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the Cincinnati Children's Hospital Medical Center Web site Phone triage form for child with acute gastroenteritis (AGE). Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2012. 1 p. Electronic copies: Available in PDF from the Cincinnati Children's Hospital Medical Center Web site Acute gastroenteritis inpatient order set template. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2012. 1 p. Electronic copies: Available in PDF from the Cincinnati Children's Hospital Medical Center Web site Table of evidence levels. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center Grading a body of evidence to answer a clinical question. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center Judging the strength of a recommendation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center
Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.
Additional implementation tools, including proposed process and outcome measures, computerized provider order entry forms, history taking tool, and a model form for phone triage can be found in the original guideline document.
Patient Resources
The following Health Topics are available:
 Gastroenteritis. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 Jun. Electronic copies: Available from the Cincinnati Children's Hospital Medical Center Web site Acute diarrhea. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 Sep. Electronic copies: Available from the Cincinnati Children's Hospital Medical Center Web site

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide

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NGC Status

This summary was completed by ECRI on September 1, 1998. The information was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on March 18, 2002, and reviewed by the guideline developer as of May 7, 2002. This summary was updated by ECRI on December 19, 2005. The updated information was verified by the guideline developer on January 9, 2006. This summary was updated by ECRI on July 14, 2006. The updated information was verified by the guideline developer on July 21, 2006. This NGC summary was updated on March 28, 2012. This summary was updated by ECRI Institute on September 10, 2012 following the U.S. Food and Drug Administration advisory on Ondansetron (Zofran). This summary was updated by ECRI Institute on December 12, 2012 following the U.S. Food and Drug Administration advisory on Ondansetron (Zofran).

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